HYDROGEL FOR THE THERAPEUTIC TREATMENT OF ANEURYSMS

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to treatment of vascular aneurysms, and more particularly concerns the use of hydrogels for use in occluding aneurysms and in controlled drug delivery for treatment of aneurysms.

2. Description of Related Art

Aneurysms have been traditionally treated with externally placed clips, or internally by detachable vasoocclusive balloons or an embolus generating vasoocclusive device such as one or more vasoocclusive coils. The delivery of such vasoocclusive devices can be accomplished by a variety of means, including via a catheter in which the device is pushed through the catheter by a pusher to deploy the device. The vasoocclusive devices can be produced in such a way that they will pass through the lumen of a catheter in a linear shape and take on a complex shape as originally formed after being deployed into the area of interest, such as an aneurysm. In current techniques, the vasoocclusive devices take the form of spiral wound wires that can take more complex three dimensional shapes as they are inserted into the area to be treated. By using materials that are highly flexible, or even super-elastic and relatively small in diameter, the wires can be installed in a micro-catheter in a relatively linear configuration and assume a more complex shape as it is forced from the distal end of the catheter.

Adhesives that have been introduced to help heal aneurysms include cyanoacrylates, gelatin/resorcinol/formol, mussel adhesive protein and autologous fibrinogen adhesive. Fibrin gels have also been used as sealants and adhesives in surgery, and hydrogels have been used as sealants for bleeding organs, and to create tissue supports for the treatment of vascular disease by the formation of shaped articles to serve a mechanical function. Catheters have commonly been used to introduce such therapeutic agents locally at diseased occluded regions of the vasculature to promote vessel healing. Typically a polymeric paving and sealing material in the form of a monomer solution, prepolymer solution, or as a preformed or partially preformed polymeric product, is introduced into the lumen of the blood vessel and positioned at the point of a stenosis. The polymeric material typically can incorporate additional therapeutic agents such as drugs, drug producing cells, cell regeneration factors, and progenitor cells either of the same type as the vascular tissue of the aneurysm, or histologically different to accelerate the healing process.

Hydrogels have also been used to form expanding, swelling stents, and as space-fillers for treatment of vascular aneurysms in a manner similar to other types of mechanical, embolus generating vasoocclusive devices. In one such procedure, an aneurysm is treated by inserting a stent formed of a hydrogel material into the vessel, and then hydrating and expanding the hydrogel material until the stent occludes the vascular wall, sealing it from the parent vessel. Biodegradable hydrogels have also been used as controlled-release carriers for biologically active materials such as hormones, enzymes, antibiotics, antineoplastic agents, and cell suspensions.

From the above, it can be seen that vasoocclusive devices and materials and their deployment systems provide valuable treatments for diseased vascular regions. However, there remain important limitations in the technology presently available, since treating an aneurysm with adhesive or occluding the aneurysm with a stent may not be completely effective in healing the vascular damage. Furthermore, when an embolus generating vasoocclusive device or space-filling device such as a vasoocclusive coil is used to treat an aneurysm, the ability to treat the aneurysm depends upon whether the embolus generating vasoocclusive device can migrate out of the aneurysm through the neck of the aneurysm. It would therefore be desirable to provide a method for sealing off the neck of an aneurysm or all of the aneurysm, either in addition to or as an alternative to the introduction of a vasoocclusive device in the aneurysm, in order to prevent the danger of migration of an embolus generating device out of the aneurysm, to avoid the danger to a patient from the bursting of the aneurysm, and to promote healing of the diseased vasculature, in a manner that can be visualized under fluoroscopy. The present invention meets these and other needs.

SUMMARY OF THE INVENTION

The present invention solves these and other problems by providing, in its broadest aspect, an improved method for treating an aneurysm by delivering a hydrogel carrying growth factors to promote cellular growth across the neck of the aneurysm, to eliminate and heal the aneurysm with the body's own cellular growth. In addition to delivering the growth factor, the hydrogel acts as an embolic agent blocking the flow of blood into the aneurysm and eliminating the chance for hemorrhage, and can be used either separately, or in combination with other occlusive, embolus generating devices in treatment of aneurysms.

Briefly, and in general terms, a presently preferred embodiment of the present invention provides for a method for the treatment of aneurysms nonmechanically, through the delivery of human growth factors and/or gene therapy to the site of an aneurysm. The invention utilizes a hydrogel that acts as a carrier for both a radiopaque agent allowing the hydrogel to be visualized under fluoroscopy and a therapeutic agent such as one or more human growth factors. The hydrogel is delivered through a catheter into the aneurysm, where, in one currently preferred embodiment, the hydrogel becomes more viscous upon reaching body temperature, or upon exposure to bodily fluids. In our presently preferred embodiment, the hydrogel is constituted so as to remain a liquid at temperatures below about 37° C., to thereby facilitate the placement and retention of the gel and gel contained agents within the aneurysm. The hydrogel preferably then solidifies to block blood flow into the aneurysm. In addition to stopping blood flow into the aneurysm, the delivery of human growth factors to the aneurysm site promotes the growth of a cellular layer across the neck of the aneurysm. The hydrogel may be of a type that dissolves over time or one which remains as a permanent occlusive agent within the aneurysm.

These and other aspects and advantages of the invention will become apparent from the following detailed description.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Treatment of an aneurysm by sealing it with adhesive, blocking it with a stent, or placement of a vasoocclusive device to occlude it may not be completely effective in healing the vascular damage. A vasoocclusive or space-filling device placed within an aneurysm can also migrate out of the aneurysm through the neck of the aneurysm.

The invention accordingly provides for a hydrogel that acts as a carrier for both a radiopaque agent allowing the